Restriction Practice
Considerations in Patent Drafting and Prosecution

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Topics

• Basic Restriction Requirements
• Generic and Linking Claims
• Alternative Language and “Markush Practice”
• Petitions and Appeals
• Rejoinder Opportunities
• Case Studies and Recommendations
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35 U.S.C. 101

“Whoever invents or discovers any new and useful process, machine, manufacture, composition of matter, or any new and useful improvement thereof, may obtain a patent therefor,….”
MPEP 800

• Restriction and Double Patenting
  – Restriction In Applications Filed Under 35 U.S.C. 111
    • One invention per patent; not two inventions in one patent (except where lacking burden)
  – Double Patenting
    • One patent per invention; not two patents for one invention
No Double Patenting if Restriction

- 35 U.S.C. 121 authorizes the Director to restrict the claims in a patent application to a single invention, and the third sentence of 35 U.S.C. 121 prohibits the use of a patent issuing on an application with respect to which a requirement for restriction has been made, or on an application filed as a result of such a requirement, as a reference against any divisional application.

- A restriction requirement nullifies any double patenting rejection (statutory or non-statutory) with respect to an application and any divisional applications filed therefrom.

- A restriction also nullifies any potential double patenting invalidity grounds regarding any issued patents that may subsequently issue based on such designations (subject to the conditions set forth in MPEP 804.01).
Basic Restriction Requirements

• Restriction is a discretionary tool to limit the examination to one of a plurality of claimed inventions under 35 USC 121

• Restriction is between inventions not claims. The claims merely define the inventions
Basic Restriction Requirements Cont.

• There are two criteria for a proper requirement for restriction between patentably distinct inventions:
  • The inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(i)); and
  • There must be a serious burden on the examiner if restriction is required (see MPEP § 803.02, § 806.04(a) - § 806.04(i), § 808.01(a), and § 808.02).
Basic Restriction Requirements Cont.

• Independent Inventions
  – Not disclosed as capable of use together
  – Not disclosed as connected in design, operation or effect
  – MPEP 806.04, 808.01
  – Facts relied on to establish independence may also support the reason(s) for insisting upon restriction (burden) (MPEP 808.01)
• Related Invention Relationships:
  1. Subcombinations useable together (MPEP 806.05(d))
  2. Combination/Subcombination (MPEP 806.05(a),(c))
  3. Process and Apparatus for its Practice (MPEP 806.05(e))
  4. Product and Process of Making (MPEP 806.05(f))
  5. Apparatus and Product Made (MPEP 806.05(g))
  6. Product and Process of Using (MPEP 806.05(h))
  7. Related Products/Processes - Intermediate/Final Product/Process (MPEP 806.04(j))
  8. Product, Process of Making and Process of Using (MPEP 806.05(i))
Obvious Variants are Not Distinct Inventions

- Distinctness between related inventions requires that at least one invention would not have been obvious over the other (not obvious variants)
- If the claims are obvious restriction is not proper
  - The examiner should reject the claims as unpatentable
    - (MPEP 806.04(h))
Test for Species

- Species are distinct when:
  - Each species, as claimed, requires a mutually exclusive characteristic (MEC) not required for the other species (i.e. do not overlap in scope - 102); and
    - Related inventions in the same statutory class are considered mutually exclusive, or not overlapping in scope, if a first invention would not infringe a second invention, and the second invention would not infringe the first invention. MPEP 806.05
  - The species, as claimed, are not obvious variants of each other – 103
  - MPEP 806.04(f)
When can MEC Apply?

Yes:

- Species recited in separate claims
- Species disclosed in the specification
- Related products/related processes
- Intermediate/Final products
- Subcombinations useable together

No:

- Combination/subcombination
- Apparatus and product made
- Product and process of making
- Product and process of using
Basic Restriction Requirements - Burden

- Criteria for Burden (MPEP 808.02)
  1. Separate classification
  2. Separate status in the art
  3. Divergent field of search
- Additional criteria:
  4. If the prior art applicable to one invention would not likely be applicable to another invention
  5. the inventions are likely to raise different non-prior art issues under 101 and/or 112, 1
Linking Claims

• Definition: One or more claims inseparable from claims to two or more otherwise properly divisible inventions. MPEP 809.

• Effect: When found allowable, linking claims prevent maintaining a restriction requirement between inventions that are otherwise divisible.
Linking Claims – Types
(MPEP 809.02 and 809.03)

- Genus claims linking species claims (809.02 and 809.03)
- Claim to the necessary process of making a product linking proper process and product claims (product and process of making are not patentably distinct) (MPEP 809.03; see also 806.05(f) In re Ochiai Rejoinder below)
- Claim to “means” for practicing a process linking proper apparatus and process claims (MPEP 809.03)
- Claim to the product linking a process of making and a process of using (MPEP 809.03)
Linking Claims

• If a generic or linking claim is subsequently allowed, the restriction requirement **MUST be withdrawn**, even where claims to non-elected linked inventions have been canceled. The indication of withdrawal must also be clearly stated on the record.

• When a restriction requirement is withdrawn, 35 USC 121 no longer shields claims from double patenting considerations.

• Double patenting situations may arise where the restriction requirement was made subject to the nonallowance of generic or other linking claims which are then subsequently allowed and the restriction is then withdrawn.
Claim 1. A composition for reducing HIV viral load in an HIV infected patient, comprising an agent inhibiting viral replication and a pharmaceutically acceptable carrier

Claim 2. The composition of claim 1, wherein the agent is a polypeptide having the amino acid sequence of SEQ ID NO:2

Claim 3. The composition of claim 1, wherein the agent is a polynucleotide having the sequence of SEQ ID NO:5

Claim 4. The composition of claim 1, wherein the agent is 3,3’-methoxysilyl-3,3’-organophosphate
• Claim 1. A method for treating a neurodegenerative disorder comprising administering a peptide conjugate to a patient.
• Claim 2. The method of claim 1, wherein the neurodegenerative disorder is Alzheimer’s disease.
• Claim 3. The method of claim 1, wherein the neurodegenerative disorder is multiple sclerosis.
• Claim 4. The method of claim 1, wherein the neurodegenerative disorder is encephalitis.
Linking Claims - Notes

• Applicant is entitled to retain claims directed to non-elected inventions

• If a linking claim is allowed, examination must extend to the linked non-elected inventions

• At that time, the restriction requirement is withdrawn and the linked inventions are rejoined together
Genus or Generic Claim

• A claim that encompasses two or more disclosed embodiments (species) within its scope is considered to be a generic or genus claim (See MPEP 806.04(d) and (e))

• Two types of generic claims are:
  – Those which use alternative language to enumerate species, i.e., Markush claims
    • Alternatives may be
      – “selected from the group consisting of A, B and C”; or
      – Listed as “A, B, or C”
    • Those which do not use alternative language; instead they describe the genus using generic terminology
Three Ways to Claim a Genus

• Encompassed by a generic claim that does not use alternative language; the claim which reads upon but is not necessarily limited to plural species disclosed in the specification.
  – Claim 1, a citrus fruit.

• As a Markush claim listing plural species
  – Claim 2, a citrus fruit selected from the group consisting of an orange or a lemon.

• As a series of single species claims
  – Claim 3, an orange.
  – Claim 4, a lemon.
Markush Practice

- Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).
Markush Practice

- Markush Language – Ex. “selected from the group consisting of...” or “any of A, B, or C”.

- Apply *In re Harnisch* test for “unity of invention” See MPEP 803.02
  - Compounds have a common utility
  - Compounds as a whole have a substantial structural similarity
Markush Practice – Example

• Unity exists under *Harnisch* test

Claim 1: A method of treating diabetes comprising administering compound X and further administering a compound selected from the group consisting of A, B and C.

Disclosure: A, B and C have similar function and have a common structure.
If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions.

Should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush type claim will be extended.
MPEP 821.04 (b)

Proper restriction between product and process claims

Applies only where product claims are elected

Requires allowable product claim

Applies only to process claims that depend from or include all the limitations of the allowable product claim
If application discloses both product and process(es) of making and/or using, but claims the product only and a product claim is allowed, process claims may be entered prior to final rejection.

After final rejection is governed by 37 CFR 1.116.

After allowance practice is governed by 37 CFR 1.312.
In re Ochiai Rejoinder

• Rejoinder by the Office is *sua sponte*

• Less than all pending process claims may be rejoined where less than all process claims include all the limitations of the allowable product.

• Obviousness double-patenting may be applied where product and process claims are *voluntarily* filed in separate applications.
Other Rejoinder Situations

• MPEP 806.05(c)

• Combination/subcombination inventions when an evidence claim is found to be non-allowable

• If a claim to Bsp* is determined to be allowable, any claims requiring Bsp, including any combination claims of the format ABsp, must be considered for rejoinder. See MPEP § 821.04.

*sp refers to specific; br refers to broad see MPEP 800
Appeals

• To challenge the merits of a restriction requirement, Applicants may file a petition reviewed by the Director
  – Petition is first reviewed by the examiner and SPE who prepare a brief for review by the Director

• Restriction of the subject matter in a single claim may be reviewed by the BPAI and the courts
Drafting Points and Case Studies

• Draft linking and generic/genus claims
  – Functional claiming
  – Generic terms
  – Common components
  – Combination/Subcombination
  – Intermediate manufacture claims
  – Method vs apparatus claims
Drafting Points and Case Studies

• Consider Fee Schedule
  – File independent inventions as separate applications

• Anticipate restrictions and consider resulting claim real estate
  – subcombination(s) - combination claims
    • Be judicious with dependent claim realestate in potentially restrictable subject matter
    • Consider dependent combination claim as opposed to independent combination claim.
  – Refrain from redundant claim sets
    • Can damage expanding claims be presented in dependent form?
    • Consider perspective and how claim is infringed as to value
Drafting Points and Case Studies

• Consider rejoinder
  – Processes of use/manufacture as dependent claims from the product to carry amendments to product (final/allowance)
    • A method of making the product of claim 1.
    • A method of using the product of claim 1.
  – Consider dependent combination claim from subcombination AspBbr
  – Do not cancel claims with possibility of rejoinder
• Consider drafting Markush claims for inventions with similar compounds or sequences
  – Examiner may require Applicant to elect a single species from the Markush group for searching purposes, but if no art anticipates or renders the election obvious, the entire Markush claim must be examined
Prosecution Points and Case Studies

• Notice the correct rule-
  – For applications filed under 35 USC 111, 35 USC 121 is relevant
  – For applications filed under 35 USC 371, 35 USC 372 and 35 USC 121 are relevant
  • When a continuation or divisional is filed under 35 USC 111 based on a 371, 35 USC 121 is relevant
• If the inventions, now being restricted, were searched and examined together in either the current application or a parent, it is difficult to justify the assertion of burden
Prosecution Points and Case Studies

• Consider whether the RR is proper
  – Is there overlap?
  – Is burden established?
  – Is the relation of claimed inventions correct?
  – Is the distinctiveness/independence and non-obviousness explained?

• Must traverse to petition, petition to appeal RR, and must petition prior to appeal or allowance
Prosecution Points and Case Studies

- Make a strategic election
  - Sometimes the narrowest election is the best election
  - Consider election of product for rejoinder of method
  - Consider whether invention is more likely to be patentable in method or product form
    - Is point of novelty structural or functional?
  - Consider the infringement of elected invention
    - Who
    - How much
    - When
Prosecution Points and Case Studies

- Consider an amendment in connection with the response to RR to modify the claims, such as the points discussed in the Drafting section of this presentation ("withdrawn and amended")
  - Place combination claims in dependent form
  - Place method claims in dependent form from the product claim
  - Introduce a linking/generic claim (careful)
Prosecution Points and Case Studies

• Review elections throughout duration of prosecution
  – Election by previous presentation
  – Office generally does not permit shift even if an RCE is filed - MPEP 819
• Response is held non-responsive
Final Questions

• Does the USPTO’s position of non-obviousness in a Restriction Requirement say anything about the patentability of a claimed invention over a combination of the prior art?
  • Example:
    – RR says element A is distinct and non-obvious from element B as sub combinations useable together.
    – Applicant elects combination claim C1 comprising A and B.
    – Examiner finds A in R1 and B in R2 and rejects claim C1 as obvious in view of R1 and R2 with classic KSR reasoning.
    – Can the RR be used to traverse this holding of obviousness?
Final Questions Cont.

• If so:
  – Can claims be drafted to attract a RR in anticipation of refuting such a later combination of prior art in an action on the merit?
  – Example:
    • A time machine comprising a (A) 1.21 gigawatt flex capacitor and (B) Delorean exists as prior art
    • Invention is a time machine comprising (A) a 1.22 gigawatt flex capacitor and (B) a 2012 blue Shelby Mustang.
The End